

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Ian David Manger et al.

Application No.: 10/602,489

Filed: June 23, 2003

For: RECIRCULATING FLUIDIC
NETWORK AND METHODS FOR
USING THE SAME

Customer No.: 20350

Confirmation No. 1122

Examiner: Paul Sang Hwa Hyun

Technology Center/Art Unit: 1772

STATEMENT OF REASONS IN
SUPPORT OF PRE-APPEAL BRIEF
REQUEST FOR REVIEW

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Commissioner for Patents
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Commissioner:

Further to the Notice of Appeal and the Pre-Appeal Brief Request for Review submitted herewith, Applicant submits the following arguments in support of the Pre-Appeal Brief Request for Review.

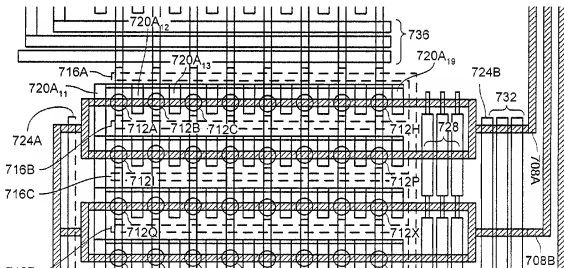
Pending claims 14, 15, 18-20, 23-26, 28-31, 34-37, 39, and 40 are rejected under 35 USC § 103(a) as being unpatentable over Van Dam et al. (US 2003/0008411 A1) in view of Quake et al. (US 2002/0037499 A1). Applicants respectfully traverse the rejections.

As set forth in detail below, Applicants submit that the Final Office Action mailed April 15, 2011 ("the Final Office Action") incorrectly characterized the secondary reference, failed to comply with MPEP 2143.03, and used impermissible hindsight. Accordingly, Applicants respectfully request that the rejections be overturned. (For the sake of brevity, certain arguments presented in response to prior Office Actions are not presented herein; Applicant reserves the right to present these additional arguments in a formal appeal brief).

Claim Rejections under 35 USC § 103

Claim 14 is drawn to a method of conducting a binding assay and FIG. 7A, a portion of which is reproduced below, illustrates an embodiment of the present invention. The method includes, among other steps, transporting a sample solution through flow channels using a pump (e.g., pump 732 in FIG. 7A). Once the sample solution is present in the flow channels, one of the control channels of the pump (e.g., control channel 724B) and a second valve (e.g., valve 724A) are used to form one of a plurality of closed loops. The sample solution is then recirculated within the closed loop using a recirculating pump (e.g., recirculating pump 728). It should be noted that the pump used to transport sample solution to the flow channels (e.g., pump 732) is *outside* the closed loop. The recirculating pump (e.g., recirculating pump 728) is *inside* the closed loop, as appropriate for recirculating fluid once the closed loop is formed.

FIG. 7A



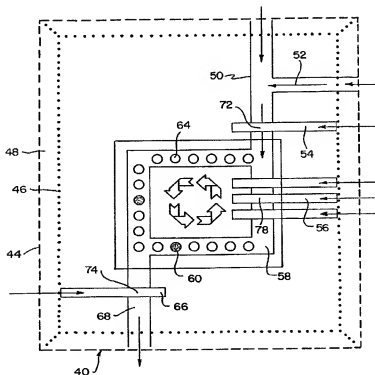
Claim 14 recites a particular implementation in which "the first valve of the set of loop forming control valves [e.g., control valve 724B] comprises a control channel of the pump [the third (i.e., left-most) control channel of pump 732]," among other elements. Thus, control valve 724B serves a dual function as both a first valve of the set of loop forming control valves (724B & 724A) as well as a control channel of pump 732. The use of one of the control channels of the external pump as a valve to form a closed loop is not taught or suggested by either Van Dam or Quake.

In the Final Office Action, the Examiner admits that Van Dam does not disclose the step of manipulating the valves to form a closed loop as recited in claim 14 and attempts to use Quake to make up for this deficiency in Van Dam. Quake does discuss (in relation to FIG. 14) a mixing and/or detection loop actuated by a peristaltic pump formed of microvalves. However, Quake fails to teach or suggest a loop forming control valve that is a control channel of an external pump as recited in claim 14.

MPEP 2413.03 requires that "All words in a claim must be considered in judging the patentability of that claim against the prior art." In the Final Office Action, the Examiner makes conclusory statements that Quake teaches the claim elements despite the fact that Quake fails to teach or suggest these claim elements and thereby fails to comply with MPEP 2413.03.

As illustrated in FIG. 14 of Quake (reproduced below), microvalve 72 is used to open and close the sample inlet channel 50 and microvalve 74 is used to open and close the sample outlet channel 68, thereby forming target loop 58. Sequential operation of valves 78 is used to create a peristaltic pumping action as illustrated by the counterclockwise arrows.

FIG. 14



Quake transports the sample to closed loop 58 using a pump that is outside the outer dashed lines and not shown in FIG. 14. Quake provides no discussion in relation to FIG. 14 of the external pump that is used to transport fluid to the sample inlet channel. Microvalve 72 has no relation to the external pump and merely functions as a valve to close the sample inlet channel 50. Therefore, although Quake discusses the use of microvalves 72 and 74 to form the closed loop 58, Quake provides no discussion related to a pump in communication with and operable to transport a sample solution through flow channels, where the first valve of the set of loop forming control valves comprises a control channel of the pump.

On page 4 of the Final Office Action, the Examiner states that the "loop can be formed by actuating independently controlled elastomeric valves that can also act as a pump (see [0079])." Despite the reference to paragraph [0079] of Quake, there is no support in Quake for the Examiner's conclusion that microvalves 72 and 74 "act as a pump."

The first portion of paragraph [0079] of Quake discusses the target loop being fed by a loop inlet and drained by a loop outlet (i.e., microvalves 72 and 74). The remainder of paragraph [0079] merely discusses the peristaltic pump 78, which is internal to the closed loop. It appears that the Examiner, in attempting to find the claimed elements in Quake, has confused the claimed pump and recirculating pump, improperly using the peristaltic pump 78 of Quake to read on both the pump (external to the closed loop) and the recirculating pump recited in claim 14. This confusion results in the Examiner making several incorrect statements in the Final Office Action.

In responding to Applicant's arguments, the Examiner states on pages 6 and 7 of the Final Office Action that "Quake et al. disclose the use of independently actuated control channels that can be pressurized to form closed loop channels within its device, wherein the control channels can also be sequentially actuated to pump fluid through the closed loop channels (see [0079])." (Emphasis Added). This statement by the Examiner is clearly wrong and demonstrates the Examiner's evident confusion.

As clearly shown in FIG. 14 of Quake, the peristaltic pump 78 is located *inside* the closed loop as appropriate for creating a pumping action in the target loop 58. The microvalves 72 and 74 that form target loop 58 are *outside* the closed loop and cannot serve any

function in pumping fluid through the closed loop using peristaltic pumping. Once the valves are actuated to form the closed loop, they cannot be used to pump fluid through the closed loop.

On page 7 of the Final Office Action the Examiner then concludes: "Quake et al. disclose the feature "wherein the first valve of the set of loop forming control valves comprises a control channel of the pump," []." Quake makes no such statement and Quake's disclosure provides no suggestion that would support this conclusory statement. Quake does not teach or suggest that microvalve 72 is a portion of an external pump used to transport fluid to target loop 58. As stated above, the sole purpose discussed by Quake for microvalve 72 is to open and close the sample inlet channel. Whether through confusion or mistake, and despite the Examiner's conclusory statement, the Examiner has failed to show how Quake teaches or suggests the claim elements in compliance with MPEP 2413.03.

Applicants suggest that because the Examiner found no support in Quake for a loop forming control valve that also serves as a control channel of a pump external to the closed loop, the Examiner has evidently used Quake's discussion of loop forming control valves and peristaltic pumping as a starting point for impermissible hindsight. MPEP 2142 is very clear that any suggestion to modify a reference must be found in the prior art, and cannot be based upon Applicants' own disclosure. Here, the Examiner appears to be using impermissible hindsight.

In conclusion, Quake does not teach or suggest the use of one of the control channels of a pump outside the closed loop as a valve to form the closed loop as recited by claim 14. Claim 34 recites elements similar to claim 14. For at least these reasons, Applicants respectfully submit that the rejections of the claims are improper and should be overturned.

Respectfully submitted,

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